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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,558	10/20/2000	Elfi Biedermann	25846-0003	7777

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/693,558	BIEDERMANN ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-82* is/are pending in the application.

4a) Of the above claim(s) *65 and 72-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-64 and 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 1/8/2009, are acknowledged and entered. Claims 57-82 are pending and under examination. Claims 65 and 72-82 remain withdrawn from consideration. Claims 57-64 and 66-71 are presently under examination and are the subject of this Office Action.

Claim Rejections - 35 USC § 112 – 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 57-64 and 66-71 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is **withdrawn** in light of Applicant's amendments.

The rejection of claims 66-67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is **withdrawn** in light of Applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

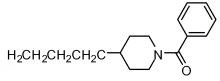
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-64 and 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over **WO 97/48397** (Published December 24, 1997) in view of **Hoskin *et al***. (British Journal of Cancer, 1997, vol. 76, pages 260-263).

The instant claims recite pharmaceutical compositions comprising a compound of Formula (I), *e.g.*, N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide, and a compound having vitamin PP activity, *e.g.*, a compound of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb. Such compounds of Formula V include the instantly elected nicotinamide.

WO '397 teaches compounds of Formula (I) for use in the treatment of tumors or for immunosuppression (Abstract). The compounds of Formula (I) are defined at pages 3-13 of WO '397 and include the instantly elected N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide as recited in instant claim 58 when R^1 is H, k is 0, A is CH_2=CH_2, R^4 is H, and D-E-G is  (Compound No. 259 in Table 2 of WO '397).

With regard to the administration forms as recited in claims 69-71, WO '397 teaches the same administration forms at pages 178-187.

The compounds of Formula (I) as disclosed in WO '397 can be combined with other chemotherapeutic agents (page 204) as well as with radiotherapy, hyperthermia, or immunotherapy (pages 204 and 206).

The inventors also teach that the compositions and methods of the invention are not limited to the respective "concretely named" active ingredient concentrations, dosages, combinations with one or more other cytostatic agents, tumor inhibitors, cancerostatic agents, immunosuppressive agents or further medicinal agents suitable for the respective specific indications or the type of tumor to be treated or immunological illness (page 206).

What WO '397 does not explicitly teach is the specific combination of a compound of Formula (I) (*e.g.*, N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide) and a vitamin PP active agent (*e.g.*, nicotinamide) as recited in the instant claims.

However, Hoskin *et al*. teach administration of nicotinamide and nicotinamide + carbogen to patients having bladder cancer undergoing radiation therapy (Abstract). The clinical results show that carbogen and nicotinamide may improve the results of daily fractionated radiotherapy in bladder cancer.

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate a composition comprising a compound of Formula (I) as taught in WO '397 and nicotinamide as taught in Hoskin *et al*. The inventors of WO '397 clearly suggest and motivate combinations of compounds of Formula (I) with other chemotherapeutic agents (page 204) as well as with radiotherapy, hyperthermia, or immunotherapy (pages 204 and 206). Hoskin *et al*. clearly teach that nicotinamide is useful when used in combination with radiotherapy for the treatment of bladder cancer. As such, one of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that a composition comprising a compound of Formula (I) and nicotinamide would be effective in treating bladder cancer when used in combination with radiotherapy. It is noted that WO '397 teaches that the compounds of the invention and their salts have therapeutic use in the treatment of solid tumors such as bladder tumors (page 203).

Applicant's arguments have been carefully considered but they are not persuasive to overcome the prima facie case of obviousness set forth above.

Firstly, Applicants argue that Hoskin does not provide any motivation to combine the teachings of Hoskin with WO '397 to arrive at the claimed composition. In this regard, Applicants argue that the only cancerostatic or immunosuppressive agent disclosed in Hoskin is radiation, which Applicants assert is not a "chemotherapeutic agent" of any kind, let alone a compound of formula I. This line of argument is not persuasive because WO '397 suggests and motivates combining compounds of formula I with other chemotherapeutic agents (page 204) as well as with **radiotherapy**, hyperthermia, or immunotherapy (pages 204 and 206). Hoskin discloses combination therapy of bladder cancer with carbogen, nicotinamide, and radiation.

This skilled artisan would reasonably expect that addition of a compound of formula I to the therapy disclosed in Hoskin would also reasonably be effective against cancer.

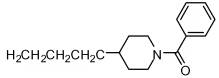
Secondly, Applicants assert that preventing the closure of small blood vessels with nicotinamide actually enhances the vitality and metastatic potential of tumors by increasing oxygenation. This is not persuasive because Hoskin teaches that carbogen, nicotinamide, and radiation are effective to treat bladder cancer. Further, preventing the closure of blood vessels in a tumor would be expected to allow increased permeation of chemotherapeutic agents into the tumor.

Thirdly Applicants argue that the teachings of Exhibit A cast doubt on nicotinamide's effectiveness as a sensitizing agent during radiation therapy, which is nicotinamide's most well-known utility in oncology. While Exhibit A does state that carbogen combined with nicotinamide was no more effective than carbogen alone, there is nothing in the cited reference suopporting Applicant's conclusion that nicotinamide is not effective to sensitize a tumor to radiation. In fact, the reference states that both carbogen and nicotinamide "have been shown to increase tumour response to radiotherapy (left column).

Accordingly, the rejection is maintained for the reasons of record and as reiterated above. The skilled artisan would have been imbued with at least a reasonable expectation that addition of a compound of formula I to the treatment method of Hoskin (carbogen, nicotinamide, and radiation) would be effective for the treatment of tumors and would have thus been motivated to formulate a composition comprising a compound of formula I and nicotinamide for use in such treatment.

Claims 57-64 and 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over **WO 97/48397** (Published December 24, 1997) in view of **Olsson *et al***. (British Journal of Cancer, 1996, vol. 74, pages 368-373).

The instant claims recite pharmaceutical compositions comprising a compound of Formula (I), *e.g.*, N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide, and a compound having vitamin PP activity, *e.g.*, a compound of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb. Such compounds of Formula V include the instantly elected nicotinamide.

WO '397 teaches compounds of Formula (I) for use in the treatment of tumors or for immunosuppression (Abstract). The compounds of Formula (I) are defined at pages 3-13 of WO '397 and include the instantly elected N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide as recited in instant claim 58 when R^1 is H, k is 0, A is CH_2=CH_2, R^4 is H, and D-E-G is  (Compound No. 259 in Table 2 of WO '397).

With regard to the administration forms as recited in claims 69-71, WO '397 teaches the same administration forms at pages 178-187.

The compounds of Formula (I) as disclosed in WO '397 can be combined with other chemotherapeutic agents (page 204) as well as with radiotherapy, hyperthermia, or immunotherapy (pages 204 and 206).

The inventors also teach that the compositions and methods of the invention are not limited to the respective "concretely named" active ingredient concentrations, dosages, combinations with one or more other cytostatic agents, tumor inhibitors, cancerostatic agents, immunosuppressive agents or further medicinal agents suitable for the respective specific indications or the type of tumor to be treated or immunological illness (page 206).

What WO '397 does not explicitly teach is the specific combination of a compound of Formula (I) (*e.g.*, N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide) and a vitamin PP active agent (*e.g.*, nicotinamide) as recited in the instant claims.

However, Olsson *et al*. teach that nicotinamide induces DNA damage and repair when administered to mice inoculated with adenotype 12 virus-induced mouse sarcoma A12B3 and sarcoma F (Abstract). Administration of between 100 and 1000 mg/kg nicotinamide causes a high level of *in vivo* DNA strand breaks in tumors and in normal tissues in mice bearing the immunogenic sarcoma A12B3. Nicotinamide also delayed the repair process of DNA strand breaks (Abstract).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate a composition comprising a compound of Formula (I) as taught in WO '397 and nicotinamide as taught in Olsson *et al*. The inventors of WO '397

clearly suggest and motivate combinations of compounds of Formula (I) with other chemotherapeutic agents (page 204) as well as with radiotherapy, hyperthermia, or immunotherapy (pages 204 and 206). Olsson *et al*. clearly teach that nicotinamide induces DNA damage and delays DNA repair when administered to mice bearing immunogenic sarcoma A12B3. As such, one of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that a composition comprising a compound of Formula (I) and nicotinamide would be effective in treating a sarcoma by inducing DNA damage and inhibiting DNA repair. It is noted that WO '397 teaches that the compounds of the invention and their salts have therapeutic use in the treatment of soft tissue sarcomas (page 203).

Applicant's arguments have been carefully considered but they are not persuasive to overcome the prima facie case of obviousness set forth above.

Firstly, Applicants argue that the fact that Olsson teaches that nicotinamide induces DNA damage and delays DNA repair does not teach or suggest that nicotinamide, when combined with a cancerostatic or immunosuppressive agent, could reduce the side effects of the cancerostatic or immunosuppressive agent. This is not persuasive because Applicants are arguing an intended use of the claimed composition. The fact that Olsson does not suggest that nicotinamide could reduce the side effects of a cancerostatic or immunosuppressive agent is not pertinent to the obviousness of the claimed compositions. One skilled in the art at the time the invention was made would have been imbued with at least a reasonable expectation that a combination of a compound of formula I and nicotinamide would be effective in the treatment of cancer as a result of both the antitumor activity of a compound of formula I as suggested by WO '397 and the DNA damaging effect of nicotinamide as suggested by Olsson.

Secondly, Applicants argue that Olsson teaches away from the use of nicotinamide because Olsson discloses that high doses of nicotinamide "might cause considerable complications to normal tissue in tumor-bearing individual". However, the fact that nicotinamide has side effects, common to almost all chemotherapeutic agents, only suggests that the skilled artisan should carefully adjust the dose of nicotinamide so as to minimize toxicity. Such does not "teach away" from using nicotinamide in cancer chemotherapy regimens.

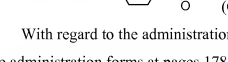
Thirdly Applicants argue that the teachings of Exhibit A cast doubt on nicotinamide's effectiveness as a sensitizing agent during radiation therapy, which is nicotinamide's most well-

known utility in oncology. While Exhibit A does state that carbogen combined with nicotinamide was no more effective than carbogen alone, there is nothing in the cited reference suopporting Applicant's conclusion that nicotinamide is not effective to sensitize a tumor to radiation. In fact, the reference states that both carbogen and nicotinamide "have been shown to increase tumour response to radiotherapy (left column).

Accordingly, the rejection is maintained for the reasons of record and as reiterated above. The skilled artisan would have been imbued with at least a reasonable expectation that a composition comprising a compound of Formula I and nicotinamide would be effective for the treatment of tumors and would have thus been motivated to formulate a composition comprising a compound of formula I and nicotinamide for use in such treatment.

Claims 57-64 and 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over **WO 97/48397** (Published December 24, 1997) and **Pero** (USP No. 5,340,565; Issued Aug. 23, 1994).

The instant claims recite pharmaceutical compositions comprising a compound of Formula (I), *e.g.*, N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide, and a compound having vitamin PP activity, *e.g.*, a compound of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va, or Vb. Such compounds of Formula V include the instantly elected nicotinamide.

WO '397 teaches compounds of Formula (I) for use in the treatment of tumors or for immunosuppression (Abstract). The compounds of Formula (I) are defined at pages 3-13 of WO '397 and include the instantly elected N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide as recited in instant claim 58 when R^1 is H, k is 0, A is CH_2=CH_2, R^4 is H, and D-E-G is  (Compound No. 259 in Table 2 of WO '397).

With regard to the administration forms as recited in claims 69-71, WO '397 teaches the same administration forms at pages 178-187.

The compounds of Formula (I) as disclosed in WO '397 can be combined with other chemotherapeutic agents (page 204) as well as with radiotherapy, hyperthermia, or immunotherapy (pages 204 and 206).

The inventors also teach that the compositions and methods of the invention are not limited to the respective "concretely named" active ingredient concentrations, dosages, combinations with one or more other cytostatic agents, tumor inhibitors, cancerostatic agents, immunosuppressive agents or further medicinal agents suitable for the respective specific indications or the type of tumor to be treated or immunological illness (page 206).

What WO '397 does not explicitly teach is the specific combination of a compound of Formula (I) (*e.g.*, N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide) and a vitamin PP active agent (*e.g.*, nicotinamide) as recited in the instant claims.

However, Pero teaches methods of inhibiting or killing tumor or cancer cells in a patient comprising administering "a chemotherapeutic agent" in combination with nicotinamide and an oxidative stressing agent (see claim 6 of Pero). Nicotinamide has been shown to be an effective sensitizer of the cytotoxic action of induced by radiation and cancer chemotherapeutic drugs (col. 2, lines 21-46).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate a composition comprising a compound of Formula (I) as taught in WO '397 and nicotinamide as taught in Pero. The inventors of WO '397 clearly suggest and motivate combinations of compounds of Formula (I) with other chemotherapeutic agents (page 204) as well as with radiotherapy, hyperthermia, or immunotherapy (pages 204 and 206). Pero clearly suggests that compositions comprising a chemotherapeutic agent, nicotinamide, and an oxidative stressing agent can be used to treat cancer in human patients. As such, one of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that a composition comprising a compound of Formula (I), nicotinamide, and an oxidative stressing agent would be effective in inhibiting or killing tumor or cancer cells in a patient. It is noted that both WO '397 and Pero suggest combination therapy comprising the compounds instantly claimed.

Applicant's arguments have been carefully considered but they are not persuasive to overcome the prima facie case of obviousness set forth above.

Firstly, Applicants argue that with respect to the chemotherapeutic agents encompassed by Pero's teaching and Pero's claim 6, it is explicitly stated that chemotherapeutic agents of interest are limited to those having cytotoxic effects resulting from the chemotherapeutic agents modulation of the catalytic activity of the enzyme adenosine diphosphate ribosyl transferase (ADPRT) (col. 1, lines 57-63). However, the Abstract of Pero explicitly states, "The effectiveness of cytostatic and/or cytotoxic drugs and/or radiation in the killing of tumor and/or cancer cells is increased by the administration, along with said drugs and radiation, of an effective activating or inhibiting amount of a compound or agent which activates or inhibits [ADPRT]". An inhibitor of ADPRT disclosed in Pero is nicotinamide (col. 1, line 67 to col. 2, line 3; col. 2, lines 21-65). As such, because Pero suggests and motivates the use of a cn inhibitor of ADPRT such as nicotinamide to enhance the effectiveness of cytostatic and/or cytotoxic drugs and/or radiation in the killing of tumor and/or cancer cells, the skilled artisan would have been imbued with at least a reasonable expectation that nicotinamide in combination with the cytostatic drugs of Formula I disclosed in WO '397 would be effective in the treatment of cancer as suggested and motivated by the cited prior art.

Secondly, Applicants argue that there is no disclosure in Pero of the desirability of employing compounds that result in oxidative stress and thus absent a teaching or scientific rationale suggesting that the combination of Pero's claim 6 is effective in the absence of the oxidizing stress agent, persons of ordinary skill in the art would not have been motivated to specifically combine the cancerostatic compound of WO '397 with nicotinamide. The Examiner is admittedly confused by this line of argument. Why would the skilled artisan have to remove the oxidative stress agent from the method disclosed in Pero's claim 6? The instant claims recite comprising language, which allows for the presence of other active agents in the claimed compositions. Thus, the skilled artisan need only add a compound of Formula I as disclosed in WO '397 to a composition comprising nicotinamide and an oxidative stressing agent as suggested and motivated by Pero to arrive at a composition as instantly claimed.

Thirdly, Applicants allege that Pero merely provides a research scheme for creating a hypothetical class of compounds that are similar to nicotinamide, i.e., nicotinamide derivatives, not nicotinamide per se. Applicants cite Exhibits B-F to chow the difference in structure between nicotinamide and xanthine, theophylline, purine, and metoclopramide. Applicants

assert that Pero's rationale for nicotinamide's use as a chemosensitizing agent during chemotherapy is speculative at best and runs counter to the controlling case law on the subject. However, this argument appears to ignore the fact that Pero explicitly teach a method of inhibiting or killing tumor or cancer cells in a human subject comprising treating the subject with a chemotherapeutic agent or radiation while administering to the patient, in combination, **nicotinamide** and an oxidative stressing agent (claim 6). Thus, Pero clearly discloses the use of nicotinamide *per se* in combination therapy regimens for treating tumors and cancer. Applicants have presented no factual evidence to support their assertion that such a method would not work as described in Pero.

Fourthly, Applicants argue that the teachings of Exhibit A cast doubt on nicotinamide's effectiveness as a sensitizing agent during radiation therapy, which is nicotinamide's most well-known utility in oncology. While Exhibit A does state that carbogen combined with nicotinamide was no more effective than carbogen alone, there is nothing in the cited reference suopporting Applicant's conclusion that nicotinamide is not effective to sensitize a tumor to radiation. In fact, the reference states that both carbogen and nicotinamide "have been shown to increase tumour response to radiotherapy (left column).

Accordingly, the rejection is maintained for the reasons of record and as reiterated above. The skilled artisan would have been imbued with at least a reasonable expectation that a composition comprising a compound of Formula I, nicotinamide, and an oxidative stressing agent would be effective for the treatment of tumors and would have thus been motivated to formulate a composition comprising a compound of formula I, nicotinamide, and an oxidative stressing agent for use in such treatment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614